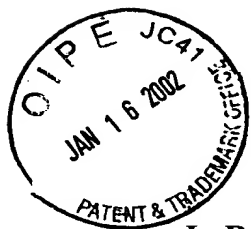


DOCKET NO.: TJU-2415



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

1645
#8
RECEIVED
JAN 22 2002
TECH CENTER 1600/2900

In Re Application of:

Scott A. Waldman, et al.

Serial No.: 09/819,248

Group Art Unit: 1645

Filing Date: March 27, 2001

Examiner: Not Yet Assigned

For: **USE OF EXPRESSION PROFILING FOR IDENTIFYING MOLECULAR
MARKERS USEFUL FOR DIAGNOSIS OF METASTATIC CANCER**

DATE OF DEPOSIT: 14 Dec 2001

I HEREBY CERTIFY THAT THIS PAPER IS BEING
DEPOSITED WITH THE UNITED STATES POSTAL
SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID
ON THE DATE INDICATED ABOVE AND IS ADDRESSED
TO THE ASSISTANT COMMISSIONER FOR PATENTS,
WASHINGTON, DC 20231.

Ellen M. Klann

TYPED NAME: Ellen M. Klann
REGISTRATION NO.: 44,836

Assistant Commissioner for Patents
Washington DC 20231

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).



In accordance with §1.97(b), since this Information Disclosure Statement is being

filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first office action after the filing of request for continued examination under §1.114, no additional fee is required.

- ☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐the first or ☐second After Final Submission, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or before an action that otherwise closes prosecution in the application, therefore:
- ☐ Certification in Accordance with §1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in §1.17(p) is attached.
- ☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); and the submission fee of \$180.00 as set forth in §1.17(p).
- ☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.


- ☐ In accordance with §1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. §120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. , filed .
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050.

This form is submitted in duplicate.

There are no listed references which are not in the English language.

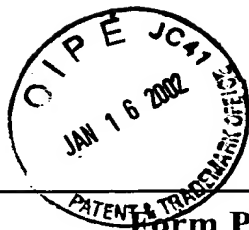
Date: 14 Dec 2001



Ellen M. Klann

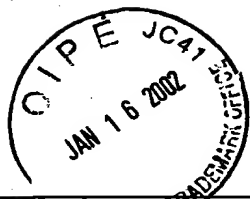
Registration No. 44,836

WOODCOCK WASHBURN, LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2415	Serial No. 09/819,248	RECEIVED JAN 22 2002 TECH CENTER 1600/2900
		Applicant Scott A. Waldman, et al.		
		Filing Date March 27, 2001	Group 1645	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
	AA	Abati and Liotta, "Looking forward in diagnostic pathology", <i>Cancer</i> , 1996 , 78, 1-3		
	AB	Adams, M.D. et al., "Serial analysis of gene expression: ESTs get smaller", <i>Bioessays</i> , 1996 , 18, 261-262		
*	AC	Ausubel, et al., "Current protocols in Molecular Biology," <i>John Wiley & Sons, Inc.</i> , NY, 2000		
*	AD	Ausubel, et al., "Current protocols in Molecular Biology," <i>John Wiley & Sons, Inc.</i> , NY, 1999		
	AE	Bach, I., et al., "Cloning of human hepatic nuclear factor 1 (HNF1) and chromosomal localization of its gene in man and mouse", <i>Genomics</i> , 1990 , 8, 155-164		
	AF	Barnes, W.M., "PCR amplification of up to 35-kb DNA with high fidelity and high yield from bacteriophage templates", <i>Proc. Natl. Acad. Sci. USA</i> , 1994 , 91, 2216-2220		
	AG	Beck, F. et al., "Reprogramming of intestinal differentiation and intervalary regeneration in Cdx2 mutant mice", <i>PNAS</i> , 1999 , 96, 7318-7323		
	AH	Brenner, S. et al., "Gene expression analysis by massively parallel signature sequencing (MPSS) on microbead arrays", <i>Nature Biotech.</i> , 2000 , 18, 630-634		
	AI	Carrithers, et al., "Guanylyl cyclase C is a selective marker for metastatic colorectal tumors in human extraintestinal tissues", <i>Proc. Natl Acad Sci. USA</i> , 1996 , 93, 14827-14832		
	AJ	Chartier, F.L., et al., "coning and sequencing of cDNAs encoding the human hepatocyte nuclear factor 4 indicate the presence of two isoforms in human liver" <i>Gene</i> , 1994 , 147, 269-272		
EXAMINER		DATE CONSIDERED		

* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.



RECEIVED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2415	Serial No. 09/819,248
		Applicant Scott A. Waldman, et al.	
		Filing Date March 27, 2001	Group 1645
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AK	Chawengsaksophak, et al., "Homeosis and intestinal tumours in Cdx2 mutant mice" <i>Nature</i> , 1997 , 386, 84-87	
	AL	Cheng, S. et al., "Effective amplification of long targets from cloned inserts and human genomic DNA", <i>Proc. Natl. Acad. Sci. USA</i> , 1994 , 91, 5695-5699	
	AM	Cheung, V.G. et al., "Making and reading microarrays", <i>Nature Genetics</i> , 1999 , 21 (Suppl.), 15-19	
	AN	Diatchenko, L. et al., "Suppression subtractive hybridization: A method for generating differentially regulated or tissue-specific cDNA probes and libraries", <i>Proc. Natl. Acad. Sci. USA</i> , 1996 , 93, 6025-6030	
	AO	Endege, W.O. et al., "Representative cDNA libraries and their utility in gene expression profiling", <i>Biotechniques</i> , 1999 , 26, 542-550 (missing pages are ads)	
	AP	Gurskaya, N.G. et al., "Equalizing cDNA subtraction based on selective suppression of polymerase chain reaction: Cloning of jurkat cell transcripts induced by phytohemagglutinin and phorbol 12-myristate 13-acetate", <i>Anal. Biochem.</i> , 1996 , 240, 90-97	
	AQ	Gygi, S.P. et al., "Quantitative analysis of complex protein mixtures using isotope-coded affinity tags", <i>Nature Biotech.</i> , 1999 , 17, 994-999	
	AR	Gygi, S.P. et al., "Measuring gene expression by quantitative proteome analysis", <i>Curr. Opinion in Biotech</i> , 2000 , 11, 396-401	
*	AS	Hames, et al., "Gene Transcription: A Practical Approach," <i>The practical Approach Series</i> , New York: Oxford University Press, 1993	
	AT	Heinemeyer, T. et al., "Databases on transcriptional regulation: TRANSFAC, TRRD and COMPEL", <i>Nucleic Acids Res.</i> , 1998 , 26, 362-367	
EXAMINER		DATE CONSIDERED	

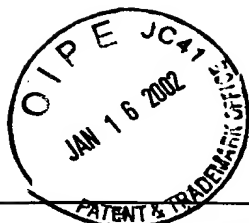
* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.



RECEIVED

PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2415	Serial No. 09/819,248
		Applicant Scott A. Waldman, et al.	
		Filing Date March 27, 2001	Group 1645

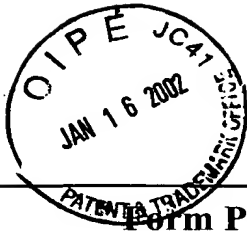
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AU	Hou, J., et al., "Identification and purification of human stat proteins activated in responses to interleukin-2", <i>Immunity</i> , 1995 , 2, 321-329	
AV	Kritis, A.A., et al., "Isolation and characterization of a third isoform of human hepatocyte nuclear factor 4", <i>Gene</i> , 1996 , 173, 275-280	
AW	Kroczeck, J., "Southern and Northern analysis", <i>Chromatog</i> , 1993 , 618, 133-145	
AX	Liang, P. et al., "Differential display of eukaryotic messenger RNA by means of the polymerase chain reaction", <i>Science</i> , 1992 , 257, 967-970	
AY	Lie, Y.S. et al., "Advances in quantitative PCR technology: 5' nuclease assays", <i>Curr. Opin. Biotech.</i> , 1998 , 9, 43-48	
AZ	Liefers, et al., "Micrometastases and survival in stage II colorectal cancer" <i>New Engl. J. Med.</i> , 1998 , 339, 223-228	
BA	Lin, X., et al., "Characterization and sequence analysis of the human homeobox-containing gene GBX2", <i>Genomics</i> , 1996 , 31, 335-342	
BB	Mallo, G.V., et al., "Molecular cloning, sequencing and expression of the mRNA encoding human Cdx1 and Cdx2 homeobox. Down regulation of Cdx1 and Cdx2 mRNA expression during colorectal carcinogenesis", <i>Int. J. Cancer</i> , 1997 , 74, 35-44	
BC	Mann, E.A et al., "Cell line-specific transcriptional activation of the promoter of the human guanylyl cyclase C/heat-stable enterotoxin receptor gene", <i>Biochem. Biophys Acta</i> , 1996 , 1305, 7-10	
BD	O'Farrell, P.H., "High resolution two-dimensional electrophoresis of proteins", <i>J. Biol. Chem.</i> , 1975 , 250, 4007-4021	
EXAMINER		DATE CONSIDERED



RECEIVED

JAN 22 2002
TECH CENTER 1600/2900

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2415	Serial No. 09/819,248
		Applicant Scott A. Waldman, et al.	
		Filing Date March 27, 2001	Group 1645
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	BE	Patterson, S.D. et al., "Mass spectrometric approaches for the identification of gel-seprated proteins", <i>Electrophoresis</i> , 1995 , <i>16</i> , 1791-1814	
	BF	Pearson-white, S.H., "Human MyoD: cDNA and deduced amino acid sequence" <i>Nucleic Acids Res.</i> , 1991 , <i>19</i> , 1148	
	BG	Pierrou, S., et al., "Cloning and characterization of seven human forkhead proteins:binding site specificity and DNA bending", <i>EMBO J.</i> , 1994 , <i>13</i> , 5002-5012	
	BH	Quandt, K. et al., "Matind and matinspector:new fst and versatile tools for detention of consensus matches in nucleotide sequence data", <i>Nucleic Acids Res.</i> , 1995 , <i>23</i> , 4878-4884	
	BI	Schena, M. et al., "Quantitative monitoring of gene expression patterns with a complementary DNA microarray, <i>Science</i> , 1995 , <i>270</i> , 467-470	
	BJ	Shalon, D. et al., "A DNA microarray system for analyzing complex DNA samples using two-color fluorescent probe hybridization", <i>Genome Res.</i> , 1996 , <i>6</i> , 639-645	
	BK	Sloan, J.P., "Molecules and micrometastases", <i>Lancet</i> , 1995 , <i>345</i> , 1255-1256	
	BL	Spinella, D.G. et al., "Tandem arrayed ligation of expressed sequence tags (TALEST): a new method for generating global gene expresion profiles", <i>Nucleic Acids Res.</i> , 1999 , <i>27</i> , e22 (I-VIII)	
	BM	Stoffel, M., et al., "Localization of human homeodomain transcription factor insulin promoter factor 1 (IPF1) to chromosome band 13q12.1", <i>Genomics</i> , 1995 , <i>28</i> , 125-126	
	BN	Suh, E. et al., "A homeodomain protein related to caudal regulates intestine-specific gene transcription", <i>Mol Cell. Biol.</i> , 1994 , <i>14</i> , 7340-7351	
EXAMINER		DATE CONSIDERED	



RECEIVED

JAN 22 2002
TECH CENTER 1600/2900

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. TJU-2415	Serial No. 09/819,248
Filing Date March 27, 2001		Applicant Scott A. Waldman, et al.	
Group 1645			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
BO		Tamai, Y. et al., "Colonic hamartoma development by anomalous duplication in Cdx2 knockout mice", <i>Cancer</i> , 1999 , <i>59</i> , 2965-2970
BP		Traber, et al., "Intestine-Specific gene transcription", <i>Annu Rev. Physiol</i> , 1996 , <i>58</i> , 275-297
BQ		Velculescu, V.E. et al., "Serial analysis of gene expression" <i>Science</i> , 1995 , <i>270</i> , 484-487
BR		Waldman, S.A. et al., "Heterogeneity of guanylyl cyclase C expressed by human colorectal cancer cell lines in vitro", <i>Cancer Epidemiology, Biomarkers & Preention</i> , 1998 , <i>7</i> , 505-514
BS		Wang, A. et al., "Rapid analysis of gene expression (RAGE) facilitates universal expression profiling", <i>Nucleic Acids Res.</i> , 1999 , <i>27</i> , 4609-4618
BT		Wang, M., et al., "The LIM domain homeobox gene <i>isl-1</i> : Conservation of human, hamster, and rat complementary deoxyribonucleic acid sequences and expression in cell types of nonneuroendocrine lineage", <i>Endocrinology</i> , 1994 , <i>134</i> , 1416-1422
BU		Welsh, J. et al., "Arbitrarily primed PCR fingerprinting of RNA", <i>Nucleic Acids Res.</i> , 1992 , <i>20</i> , 4695-4970
BV		Wu, W., et al., "Mutations in PROP1 cause familial combined pituitary hormone deficiency", <i>Nat. Genet</i> , 1998 , <i>18</i> , 147-149
BW		Yeager, T.R. et al., "Constructing immortalized human cell lines" <i>Curr. Opin. Biotechnology</i> , 1999 , <i>10</i> , 465-469
BX		Zhang, L. et al., "Gene expression profiles in normal and cancer cells", <i>Science</i> , 1997 , <i>276</i> , 1268-1272

EXAMINER	DATE CONSIDERED
-----------------	------------------------